IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

ROBERT JONES and KRISTA JONES	:	CIVIL ACTION
	:	
Plaintiffs,	:	08-CV-2060
	:	
v.	:	
	:	
SYNTHES USA SALES, LLC, SYNTHES USA PRODUCTS, LLC, JOHN DOES 1-5, AND ABC CORP. 1-5,	:	
	:	
Defendants.	:	

BRIEF IN OPPOSITION TO DEFENDANTS SYNTHES USA SALES, LLC AND SYNTHES USA PRODUCTS, LLC'S MOTION FOR SUMMARY JUDGMENT AND TO PRECLUDE THE TESTIMONY OF PLAINTIFF'S EXPERT WARREN LIEBERMAN

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PRELIMINARY STATEMENT

This case is about a manufacturer that sold surgical implant devices without adequate testing, warning, or sufficient robust design. After just nine (9) months from a surgery the surgical screw implanted into the patient's vertebrae failed and the patient lost his chance to resume his career, endured a repeat surgery and suffered needlessly.

Not only did the manufacturer defendant rely on inadequate testing of other products (claimed to be similar) it also represented to the Federal Drug Administration ("FDA") that this other product testing should be accepted as representative testing on the subject surgical screw. The manufacturer's corporate designee and indeed its own litigation expert admit that the purpose of the surgical screw is to achieve fixation during the expected time from when the patient's own bone should go on to union. Yet, this same manufacturer did not test the product at issue for expected force loads in a dynamic setting considering multiple directions of force (like the human spine in motion experiences). The Plaintiffs assert their suggested design parameters and manufacturing processes would have no doubt strengthened the surgical screw and increased the likelihood of avoiding a product failure.

On July 22, 2005, Plaintiff Robert Jones underwent surgery on his back to resolve extreme pain that he had been experiencing as a result of three workplace injuries to his lower back that took place between December of 2003 and February of 2005. In March of 2004, Mr. Jones began treating with Dr. Marc Levine of Trenton Orthopaedic Group for these injuries. Initially, Mr. Jones engaged in conservative therapy and even underwent three epidurals to resolve the pain in his back. These efforts were unsuccessful. The pain in Mr. Jones's back was severe and debilitating. Indeed, at one point his pain became so severe that he had to excuse himself from his two sons to go to another room and lie down to avoid crying in front of them.

At this time, Dr. Levine recommended anterior lumbar interbody fusion of L5-S1 with implantation of an anterior lumbar plate.

As part of this surgery, Dr. Levine inserted an 11 millimeter polyetheretherketone ("PEEK") device was inserted into Mr. Jones's spine. The lumbar plate was screwed into Plaintiff Robert Jones's spine by use of two 24 millimeter screws and two 26 millimeter screws. The lumbar plate and the screws utilized in the surgery were manufactured by Defendants Synthes USA Sales, LLC and Synthes USA Products, LLC (collectively "Synthes"). Initially, the surgery achieved its goal of significantly improving Mr. Jones's low back pain. Mr. Jones's medical records demonstrate that he mad made very good progress in his post-operative rehabilitation and physical therapy. While he did have some lingering discomfort, his pain levels were significantly reduced from the pre-surgery levels.

In April of 2006, approximately nine (9) months following his surgery, while reaching into a dresser drawer, Mr. Jones heard a loud, audible "pop" in his back and experienced immediate, severe pain. X-rays taken during his next visit to Dr. Levine revealed that the left screw inserted into the S1 vertebrae had failed with breakage in within the bone. *See* Synthes Exhibit P at SYNTH000237. During this visit, Dr. Levine told Mr. Jones that he had never had a surgical screw fail before. *See* Synthes Exhibit Q at p. 196:20-24. Mr. Jones's pain level returned to near his pre-surgery levels following the time he heard the audible popping noise. *See* Synthes Exhibit Q at p. 206:22 – 207:7. Approximately one month later, radiology films revealed that a second screw failed.

Because the Synthes' screw had failed, Dr. Levine prescribed a posterior stabilization procedure to allow additional time for the fusion to complete its growth. *See* Synthes Exhibit P at SYNTH000236. Dr. Levine performed this second surgery on August 4, 2006 at Robert

Wood Johnson University Hospital. While this surgery has improved Mr. Jones's pain levels from what they were following the failure of the Synthes' screw, it has not reduced his pain levels to what they were during the period following his initial surgery and prior to the failure of the Synthes' hardware.

Synthes' has moved for summary judgment arguing that its warnings were adequate and that there is no reliable evidence of a product defect. Synthes also argues that it is entitled to summary judgment because plaintiffs have failed to demonstrate the cause of their injuries. Synthes' motion repeatedly makes reference to the "race to fusion." Synthes contends that hardware such as that installed into Mr. Jones are not intended to last indefinitely and will ultimately fail in the absence of fusion. Synthes' motion is misleading in its repeated assertion that Dr. Levine agrees with Synthes' experts that "breakage of the screws resulted from plaintiff's failure to achieve bony fusion across the L5-S1 vertebral space in the ten month period following surgery." *See* Synthes brief at p. 1. This assertion is misleading because Dr. Levine testified that a fusion surgery such as that performed on Mr. Jones normally takes six months to two years to take hold. Thus, there wasn't a "failure to achieve bony fusion," rather, the fusion was not afforded the opportunity to grow properly due to the failure of the stabilization hardware.

Plaintiffs have brought suit against Synthes under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq.* Plaintiffs have asserted a simple theory of liability: a more robust screw design would have provided a more resilient, stronger screw that would have lasted long enough for a fusion to take hold. Under the "race to fusion" rationale, the Synthes' screws at issue are not strong enough to complete the race, or even get to the outer limits, based upon the timeframe set forth by Dr. Levine.

To demonstrate this theory, plaintiffs have produced reports from Metallurgical Engineer, Warren Lieberman. As Synthes has repeatedly emphasized, Mr. Lieberman is not a medical expert. He has not been proffered as such. Mr. Lieberman is a materials expert with regard to fatigue strength in metals. Mr. Lieberman has set forth multiple ways in which Synthes could have increased the fatigue strength of the Synthes' screws without any alteration of the dimensions or other physical properties of the screws. To the extent that Synthes' experts disagree with Mr. Lieberman's opinion, there is a disputed issue of material fact that demonstrates that summary judgment is inappropriate. Synthes has additionally moved to preclude the testimony of Mr. Lieberman arguing that he is unqualified and his opinions lack reliability. Both of these assertions are incorrect as Mr. Lieberman surely possesses a reasonable pretension to specialized knowledge and this motion should be denied as well.

LEGAL ARGUMENT

I. SYNTHES' MOTION FOR SUMMARY JUDGMENT SHOULD BE DENIED BECAUSE PLAINTIFFS HAVE PRESENTED SUFFICIENT EVIDENCE TO DEMONSTRATE A PRIMA FACE CASE UNDER THE NEW JERSEY PRODUCTS LIABILITY ACT

Plaintiffs have directed all of their claims against Synthes under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq*. (hereinafter "PLA"). The PLA provides:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J.S.A. 2A:58C-2.

Synthes' motion for summary judgment must fail because Plaintiffs have demonstrated that the screws installed into Mr. Jones's back were not reasonably fit, suitable or safe for their intended purpose. The screws failed well in advance of the normal time needed for a fusion, such as that performed on Mr. Jones, to take hold. Synthes did not properly warn of this danger and Plaintiffs have demonstrated that feasible alternatives could have avoided this outcome. Consequently, there are material issues of fact for a jury to decide and Synthes' motion should be denied as a matter of law.

A. The Warnings Included In the Synthes Product Label Are Facially Inadequate Pursuant to the New Jersey Products Liability Act

There is no dispute that Synthes manufactured the product and bears responsibility for the warnings that accompany the products it sells, including the screws installed into Mr. Jones's back. "A duty to warn is consonant with a manufacturer's broader duty to place in the stream of

commerce only products that are reasonably safe." Coffman v. Keene Corp., 628 A.2d 710, 718 (N.J. 1993). With regard to warning requirements, the PLA provides:

> An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.

N.J.S.A. 2A:58C-4. "[A]n adequate warning is one that includes the directions, communications, and information essential to make the use of a product safe." Freund v. Cellofilm Properties, Inc., 432 A.2d 925, 932 (N.J. 1981). Additionally, the warning must adequately address the intended use of the product as well as "the risks attendant upon all foreseeable uses." Id. at 933. In most cases, the adequacy of a warning will present a jury question. *See* Matthews v. University Loft Co., 903 A.2d 1120, 1125 (App.Div.) *certif. den.* 911 A.2d 69 (N.J. 2006).

Synthes' motion seeks to take the plain language of the PLA that applies the learned intermediary doctrine to prescription drugs and expand it to medical devices, beyond what either the New Jersey legislature or any New Jersey court has seen fit to do. There is simply no authority to suggest that under the PLA, the learned intermediary doctrine applies to medical devices. Additionally, there is no authority to support Synthes' assertion that the screws at issue constitute an "unavoidably unsafe" product as contemplated by the Restatement (Second) of Torts § 402A, comment k (1979). Whether a product is unavoidably unsafe is to be decided on a case-by-case basis. Feldman v. Lederle Laboratories, 479 A.2d 374, 383 (1984). Further, comment k immunity does not "eliminate strict liability for failure to provide a proper warning."

Id. Thus, even if a product was found to be unavoidably unsafe, "that finding may not absolve the manufacturer of its failure to warn the physician or consumer of the condition within the manufacturer's actual or constructive knowledge affecting the safety, fitness, or suitability of the [product]." Id. at 384.

The learned intermediary doctrine does not apply to medical devices, such as the failed Synthes' screws, under the Products Liability Act. Synthes' argument to the contrary should be disregarded because it does not provide any indication on how the New Jersey Supreme Court would rule on the issue and because the explicit language of the statute applies the doctrine only to prescription drugs. Additionally, Synthes has failed to meet its burden of proving its affirmative defense that the screws at issue constitute an "unavoidably unsafe" product. None of Synthes' experts have claimed that these screws are unavoidably unsafe. Simply stating that the products are not intended to last indefinitely does not suggest that they are not fit for their intended purpose.

Moreover, neither the learned intermediary doctrine nor Comment k of the Restatement (Second) of Torts § 402A, would relieve Synthes of its duty to Plaintiffs in this litigation because the warnings provided to Dr. Levine did not contain adequate information on the dangers and safe use of the product. The Synthes' screw failed in Mr. Jones's back within ten months of his initial surgery. Dr. Levine testified that a fusion takes from six months to two years to complete. Benjamin Barrall, the corporate designee of Synthes in this litigation, testified that fusion only begins to take place between three and six months following the surgery. *See* Synthes Exhibit T at p. 77:16-22. The Product Insert included in Synthes' motion for summary judgment does not set forth any suggested timeline or possible lifespan for the devices, nor does it provide an estimated timespan for a spinal fusion to take hold. The Product Insert only suggests that

breakage would only occur with "delayed union or nonunion" of the bones to be fused. Given Dr. Levine's testimony that fusion takes from six months to two years, and the screws in Mr. Jones's back failed only nine months after installation, the fusion cannot be considered to have been delayed or failed. Thus, precisely because the Package Insert does not warn that the implant could fail within the normal time period for fusion to take place, it cannot be deemed adequate. At the very least, the matter must be deemed a factual issue for a jury to determine.

Synthes cites to lengthy portions of Dr. Levine's deposition testimony in support of its contention that Dr. Levine understood the concept of a "race to fusion" in that there is a finite life expectancy of the instrumentation installed into a patient. *See* Synthes' Brief at p. 9-10. It should be noted that the line of questioning from Synthes' counsel at the point of the cited testimony, pertained to the plate of the ATB System, and not the individual screws. More importantly, none of the cited testimony refutes the idea that the instrumentation used must last long enough to allow a fusion to take place. Quite frankly, the defendant manufacturer misses the point that the issue is the failure of the screw occurred first.

There is no dispute that the fusion had not completely taken hold at the time the Synthes' screws in Mr. Jones's back failed. The very fact that there was not a full fusion at ten months does not demonstrate that the fusion had failed or was delayed. Mr. Jones's medical records demonstrate that there had been bone growth in the area of the surgery, showing that the fusion process had been working. Given Dr. Levine's testimony regarding the length of time needed for fusion to take hold, there is sufficient evidence in the record to demonstrate that the fusion had not been delayed.

Synthes also relies heavily upon the affidavits/reports of its experts to suggest that the warnings of the Product Insert are adequate. The opinions of Dr. Spielman and Dr. Zardiackas

are in conflict with the opinion of Dr. Levine, demonstrating a material factual dispute and therefore, serve as grounds for the denial of the instant motion for summary judgment. Dr. Levine never testified that there had been a delay in the fusion process for Mr. Jones. Rather, his testimony indicates that the Synthes' screw failed well within the normal time parameters for fusion to take hold. Because the Synthes Product Insert does not warn of screw failure absent a delayed or nonunion, the warning is inadequate.

B. The Record Contains Sufficient Evidence To Demonstrate That the Screws Installed Into Mr. Jones's Back Are Not Reasonably Fit, Suitable or Safe For Their Intended Purpose

In addition to containing an inadequate warning, the screws manufactured by Synthes were defectively designed. The first Synthes screw to fail, fractured in the middle of the screw at a point located within the bone. The screw failed due to fatigue because it had not been designed with sufficient strength to support the expected stresses that it would encounter during the time necessary for the intended fusion to take place. Synthes' corporate designee testified that the company essentially did no testing whatsoever of the screws at issue to determine their fatigue strength. Additionally, the tests that were conducted on the ATB System were only done on one axial plane and did not attempt to replicate any of the bending motions or multi-direction stresses that the ATB System would be subject to in a patient receiving the implant. Plaintiffs have produced reports from metallurgical engineer Warren Lieberman which adequately demonstrate that Synthes could have designed a more robust screw that would not have had any impact upon the functionality of the screws. The fractured screws remain within Mr. Jones's body and thus are unable for inspection beyond radiology films.

"A product is defective if it is not fit for the ordinary purposes for which such articles are sold and used." Scanlon v. General Motors Corp., 326 A.2d 673, 677 (1974). "In a products liability case, plaintiff has the burden of proving that: (1) the product was defective; (2) the

defect caused an injury to a plaintiff who was a foreseeable user of the product; and (3) the defect existed when the product left defendant's control." Dawson v. Bunker Hill Plaza Associates, 673 A.2d 847, 855 (App.Div.) *certif. denied* 683 A.2d 1164 (1996); *see also* Michalko v. Cooke Color & Chem. Corp, 451 A.2d 179, 183 (1982). Under New Jersey law, plaintiffs do not have to demonstrate a specific manufacturer's defect because "[i]f the proofs permit an inference that the accident was caused by some defect, whether identifiable or not, a jury issue as to liability is presented." Moraca v. Ford Motor Co., 332 A.2d 599, 601 (N.J. 1975). "To prove the existence of a defect, a plaintiff may rely on the testimony of an expert who has examined the product or offers an opinion on the product's design." Lauder v. Teaneck Volunteer Ambulance Corps., 845 A.2d 1271, 1277 (N.J.App.Div. 2004). Although it is not an independent source of liability, "[p]roof of a failure to test or of inadequate testing may be evidential as an explanation of why a design was defective." Green v. General Motors Corp., 709 A.2d 205, 216 (App.Div.) *certif. den.* 718 A.2d 1210 (N.J. 1998). "Plaintiffs who assert that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design that is both practical and feasible." Lewis v. American Cyanamid Co., 715 A.2d 967, 980 (N.J. 1998).

Under a risk/utility analysis, the question that must be asked is: "Did the manufacturer act as a reasonably prudent person by designing the item as he did and by placing it on the market in that condition, or should he have designed it to incorporate certain safety features or some other modifications?" Suter v. San Angelo Foundry & Mach. Co., 406 A.2d 140, 150 (N.J. 1979). The factors that should be considered in determining whether a product liability matter should go to a jury include: the usefulness and desirability of the product; the likelihood that the product could cause injury; the availability of a safer substitute; the ability of the manufacturer to

eliminate the risks of the product without impacting the product's usefulness or cost effectiveness; the ability of the user to avoid danger through the exercise of care; the user's anticipated awareness of the inherent dangers of the product; the feasibility of the manufacturer to spread the loss. Cepeda v. Cumberland Engineering Co., Inc., 386 A.2d 816, 826-827 (N.J. 1978). Some of these factors can constitute absolute defenses if properly demonstrated by a defendant. Roberts v. Rich Foods, Inc., 654 A.2d 1365, 1371 (N.J. 1995); *see also* N.J.S.A. 2A:58C-3a(1) to 3a(3). However, it is rare for this analysis to be decided by a court, therefore, "if the proofs supporting the position of the non-moving party and the reasonable inferences drawn therefrom reveal a contested issue of fact regarding the practicality and feasibility of a proposed alternative design, the issue should be resolved by the jury." Lewis v. American Cyanamid Co., 715 A.2d 967, 979 (N.J. 1998).

A plaintiff in a product liability action is required to provide expert testimony "where the allegedly defective product involves a complex instrumentality." Lauder v. Teaneck Volunteer Ambulance Corps., 845 A.2d 1271, 1277 (N.J.App.Div.2004).

Mr. Lieberman has opined that "a defect in the screw caused the failure which could have been prevented by a more robust design providing a more resilient stronger screw." *See* Synthes' Exhibit F at p. 3. To support this opinion, Mr. Lieberman has noted that there are a number of tests that can increase the fatigue strength of the screws at issue without any impact on the dimensions of the screw. These tests include shot peening, a widely accepted practice in engineering that is used to increase the fatigue strength of metals. Mr. Lieberman also has suggested that alternate heat treatments to the composite titanium that the screws at issue are made of could yield a finer grain size than what is produced by the mill annealing that is used by Synthes and increase fatigue strength. Additionally, Mr. Lieberman suggests that alkaline gray

anodization is a known process that can increase the fatigue strength of the metal. Synthes moves for summary judgment suggesting that these alternatives must be rejected because Mr. Lieberman did not conduct physical tests utilizing these methods for feasibility or safety.

With regard to shot peening, Mr. Lieberman's report opines that shot peening improves the fatigue life of metal as a general metallurgical principal and states that shot peening is "a process that had been used for decades." *See* Synthes' Exhibit G at p. 3. Dr. Lieberman states that shot peening:

> is a cold working process in which the surface of a component is bombarded with small spherical particles of metal, glass, or ceramic. Each piece of shot striking the metal surface acts as a tiny peening hammer in parting to the surface a small indentation or dimple. To create this dimple, the surface layer must yield in tension. Below the surface, the bulk metal in attempting to regain its original shape generates a compressive stress in the cold work surface.

See Synthes' Exhibit G at p. 3. Mr. Lieberman testified at his deposition that "The shot peening does not alter the surface. The effect is a millionth of an inch, so the effect is well within the tolerances of the manufacturer of the screw, so it would not in any way deform the screw so it would not do its locking job when it's inserted into a vertebra." *See* Synthes' Exhibit S at p. 220:11-17.

Synthes' motion for summary judgment argues that Mr. Lieberman's opinion is speculative because he has not performed any shot peening tests on the 5.5 millimeter titanium cancellous locking screws to determine if it would increase fatigue strength.[2] To attack Mr. Lieberman's opinion, Synthes argues that "stress shielding" is a process that inhibits fusion and is not desirable. However, Synthes does not argue that stress shielding would result from utilizing screws with increased fatigue strength. Synthes' cites to its expert Dr. Zardiackas and

[2] Synthes' criticism of Mr. Lieberman's failure to test the screws is somewhat ironic since Synthes did not do any testing whatsoever on the screws used in the ATB System. Rather, Synthes only tested the ATB System as a whole, never determining the fatigue strength of the component parts.

claims that if "the construct is too large or too strong" then stress shielding may occur. However, he does not specifically state that increased fatigue strength in the screws at issue would create stress shielding.

Synthes also cites to Dr. Zardiackas with regard to the impact of shot peening on the screw. Not surprisingly, Dr. Zardiackas opines that the process would damage the screw. Notably, Dr. Zardiackas does not cite to any authority as support for this position. Mr. Lieberman has opined that shot peening would not have any deforming impact upon the screw beyond a millionth of an inch and would not interfere with the ability of the screw to function. The fact that Mr. Lieberman and Dr. Zardiackas have rendered conflicting opinions regarding the impact of shot peening demonstrates an issue that is factually disputed which precludes the grant of summary judgment. *See* Gangemi v. National Health Laboratories, Inc., 701 A.2d 965, 970 (N.J.App.Div.1997). Synthes improperly argues that Mr. Lieberman's opinion should be excluded because it has no scientific support. This is simply not true and Synthes has not disputed that shot-peening is a well-established method of increasing the fatigue strength in metal. Consequently, Synthes' motion for summary judgment should be denied.

Similarly, Synthes' attacks Mr. Lieberman's opinion with regard to increasing the fatigue strength of the 5.5 millimeter titanium cancellous locking screws through the use of gray anodization. The primary manner in which Synthes attacks his opinion is through the use of it's own expert Dr. Zardiackas. Again, this dispute of expert opinions is a credibility issue for a jury to determine. Moreover, Dr. Zardiackas opines that gray annodization is not appropriate because it compromises the color coding scheme that could result in sizing errors. To suggest that a more safe implant should not be designed because a spinal surgeon might get confused about color coding is nothing short of absurd. Clearly a manufacturer of surgical implants, with only a

minimum of effort, could develop an alternate method of categorizing its parts to avoid confusion on the part of the surgeon. Such information is not beyond the ken of a layperson and no expert is needed to give that opinion.

Further, Dr. Zardiackas does not state that gray annodization would render the screws unusable. Rather, he opines that the process may increase surface lubricity which "could be undesirable for a screw meant to maintain purchase and enhance the potential for bone fusion." Dr. Zardiackas does not opine that there would be any definitive impact on the purchase of the screw that has been subject to gray annodization. Further, as Dr. Zardiackas has noted, "the ATB screw has a locking thread at the head which engages the threaded holes of the ATB plate to lock the screw and prevent the screw from backing out of the plate and the bone." Thus, Dr. Zardiackas does not make it clear what impact, if any, increased surface lubricity could have on the screws.

Rather than demonstrating a need for Mr. Lieberman's exclusion, Synthes' motion demonstrates a disputed issue of material fact that demands a denial of its motion for summary judgment.

As with shot-peening and gray annodization, Synthes' criticism of Mr. Lieberman's opinion of dye penetrant inspection does not justify summary judgment. Dye penetrant inspection is a well established method of locating defects in metal surfaces that are not visible to the naked eye. Mr. Lieberman testified that he has professional experience with dye penetrant testing in his career as an engineer so Synthes' representation that the sole support for his opinion on this issue is a Wikipedia article is misleading and inaccurate. *See* Synthes' Exhibit S at p. 224:6-19. Synthes also places emphasis on the ultrasonic testing performed by its titanium suppliers. This is also misleading in that this test is conducted on the raw metal prior to being

manufactured into the screws. Thus, flaws that may develop during the manufacturing process would not be detected by the testing done by suppliers of Synthes' titanium even though Dr. Zardiackas claims that this is "highly improbable." *See* Synthes' Exhibit S at p. 227:16-25.

Ultimately, the issue of dye-penetrant inspection and its feasibility is a dispute between Mr. Lieberman and Dr. Zardiackas. Dr. Zardiackas has produced an affidavit that states "no substance which is not biocompatible or might interfere with the sterilization process can remain on the surface." Notably, Dr. Zardiackas does not state that any chemical used in dye penetrant inspection would interfere with the sterilization process. Moreover, he does not state whether in the manufacturing process of the screws there are chemicals used – i.e. greases or oils, that lack biocompatibility.

Synthes argues that because Mr. Lieberman has not tested any of his suggested alternatives, summary judgment is appropriate. In support of its position, Synthes has cited to Oddi v. Ford Motor Company, 234 F.3d 136 (3d Cir. 2000) (applying Pennsylvania law); Kolokowski v. Crown Equipment Corp., 2009 WL 2857957 (D.N.J. 2009); and Milanowicz v. The Raymond Corporation, 148 F.Supp.2d 525 (D.N.J. 2001). These cases are inapposite to the instant matter. All of these cases involve complex instrumentalities where the plaintiffs' experts suggest modifications to complicated machinery. A screw, even a surgical screw, is not a piece of complex instrumentality. Thus, the argument that testing is a requirement is inaccurate as a matter of law. *See* Green v. General Motors Corp., 709 A.2d 205, 213-214 (N.J.App.Div.) *certif. den.* 718 A.2d 1210 (N.J. 1998) (permitting an alternative design proffered by plaintiff's expert where no testing had been performed on the proposed design). The court in Green cited to the Restatement (Third) of Torts: Products Liability § 2, at comment f noting that the plaintiff is not required to produce a prototype as part of demonstrating a feasible alternative design. Id.

Indeed, in Kolokowski, the court stated that "[w]hile failure to test his alternative designs is not dispositive, it certainly undercuts the reliability of his opinion." Kolokowski, *supra*, at p. 7. Moreover, the alternative processes that Mr. Lieberman has suggested are tested, albeit not on the surgical screws used in Mr. Jones, but are well-understood by metallurgical engineers to have the results consistent with Mr. Lieberman's opinion.

Synthes includes an argument in its motion for summary judgment that Mr. Lieberman's observation that Synthes' failed to conduct any testing of the ATB System for any stresses outside of a vertical axial plane is without basis. This argument strains reason. Mr. Lieberman's opinion is based upon the testing data (or lack thereof) produced by Synthes as well as the testimony of Synthes' corporate designee Benjamin Barrall. There is no FDA regulation that restricts the amount of testing that Synthes can perform on any of its products. Synthes criticizes Mr. Lieberman's opinion that it should have attempted to account for the various stresses that the screws would experience in a patient because it is impossible to account for all the variables that the ATB System might encounter in a patient. Quite bluntly, Synthes seems to argue that there is no need to conduct any testing at all of the product and the limited testing that they actually performed was superfluous. As noted above, "[p]roof of a failure to test or of inadequate testing may be evidential as an explanation of why a design was defective." Green, *supra*, 709 A.2d at 216. Mr. Lieberman's opinion crystallizes this evidence set forth in the documents produced by Synthes as well as the testimony of Benjamin Barrall and demonstrates why the testing performed by Synthes was inadequate. Consequently, Synthes' argument should be rejected.

II. THERE IS SUFFICIENT EVIDENCE TO DEMONSTRATE THAT PLAINTIFFS' INJURIES WERE CAUSED BY SYNTHES' PRODUCTS TO PRESENT THE MATTER TO A JURY

Mr. Jones received his first spinal surgery on July 22, 2005 which included the anterior installation of the Synthes' ATB System. This surgery had successfully resolved the chronic

lower back pain that Mr. Jones suffered from following multiple workplace related accidents. Between nine and ten months following this surgery, Mr. Jones had been placing a t-shirt into a dresser drawer when he heard an audible pop or snapping noise followed by a sensation of extreme pain which caused him to fall down, unable to move. Dr. Levine has testified that it is reasonable to believe that the snapping noise was the failure of the Synthes' screw, a component of the ATB System. As a direct result of the failure of this screw, Mr. Jones suffered through months of severe pain and had to undergo a second surgery on his back. There can be no dispute that the second surgery was necessitated due to the failure of the Synthes' screws. *See* Synthes' Exhibit P at SYNTH000236.

Cases involving injuries that immediately follow an accident do not require a medical expert to testify on causation. Sentilles v. Inter-Caribbean Shipping Corp., 361 U.S. 107, 109, 80 S.Ct. 173 (1959) (stating "The jury's power to draw the inference that the aggravation of petitioner's tubercular condition, evident so shortly after the accident, was in fact caused by that accident, was not impaired by the failure of any medical witness to testify that it was in fact the cause"). "Where the sequence of events strongly indicate a causal connection between the unexpected injury and the disability that follows, no expert medical testimony is necessary to establish the causal connection." Denneny v. Siegel, 407 F.2d 433, 441 n.15 (3d Cir. 1969) (*quoting* Yoworsky v. Charles Stores Co., Inc., 172 A.2d 822 (Pa. 1961)).

The instant matter is distinct from Fane v. Zimmer, Inc., 927 F.2d 124 (2d Cir. 1991) heavily relied upon by Synthes in support of its argument. In Fane, the plaintiff one day simply began to experience pain in the leg where the allegedly defective product had been installed. Id. at 127. Additionally, Fane was solely a failure to warn case where the plaintiffs made no effort to prove defect through inadequate warnings and lack of testing. Id. at 128 n.1. Here, the

Plaintiffs have produced an expert to demonstrate that the product at issue was defective. Further, there is a precise moment identified when Mr. Jones began suffering his pain as a result of the failed screw.

It must be noted that Plaintiffs are *not* attempting to proffer Mr. Lieberman as an expert with regard to any medical issue. Plaintiffs have not submitted Mr. Lieberman's opinion in an attempt to demonstrate causation between the defective Synthes' screws and Mr. Jones's injures.

There can be no reasonable dispute that the failure of the Synthes' screws caused Mr. Jones pain from the time he heard the audible popping noise in April of 2006 through the time of his second surgery in August of 2006. Additionally, the records of Dr. Levine clearly demonstrate that the second surgery was necessitated by the failure of the Synthes' products. These items are compensable damages under the PLA that Mr. Jones has sustained and do not need to be proven with a medical expert.

Synthes argues that Mr. Jones cannot prove that his current complaints of pain are causally related to the defective screws. Synthes ignores the months of pain that Mr. Jones endured until he underwent his second surgery. Further, following the second surgery, Mr. Jones has not experienced the level of relief otherwise afforded immediately following the first surgery. Mr. Jones has acknowledged that he did not expect to receive full relief from his pain following the first surgery. However, he has a reasonable expectation to be returned to the levels he had following that first surgery. Synthes' motion attempts to confuse the timeline of this matter. Plaintiffs do not seek to recover from Synthes for a failure to return to a pain-free state. Plaintiffs simply seek have Synthes held liable for the damages it has caused that are beyond what Mr. Jones had following the initial surgery. Because there are clear damages causally

related to the defective Synthes' screws, Plaintiffs do not need a medical expert to testify in this matter and Synthes' motion for summary judgment should be denied.

III. PLAINTIFFS' EXPERT MR. WARREN LIEBERMAN IS QUALIFIED TO TESTIFY IN THIS LITIGATION AND HIS OPINIONS ARE ADMISSIBLE

In addition to moving for summary judgment, Synthes has moved to preclude the testimony of Mr. Warren Lieberman. In support of its motion, Synthes attempts to distract attention away from the relevant issues to this litigation. Namely, that a more robust screw would not have failed in Mr. Jones's back such a screw could have been created using well established methods in metallurgical engineering. Mr. Lieberman is qualified to render an opinion on these issues having had a lengthy career in engineering. Moreover, his suggested alternative designs do not utilize novel science but known processes. The opinion and testimony of Mr. Lieberman is both reliable and admissible under the Federal Rules of Evidence. Consequently, Synthes' motion to preclude the testimony of Mr. Lieberman should be denied.

A. Legal Standard

"A district court's discretion to admit expert testimony is controlled by Fed. R. Evid. 702, 703 and 403." E.E.O.C. v. Beauty Enterprises, Inc., 361 F. Supp.2d 11, 14 (D.Conn. 2005). "The 'gatekeeping function' contemplated by Rule 702 essentially requires the trial judge to assess whether it is '*reasonably likely* that the expert possesses specialized knowledge which will assist the trier better to understand a fact in issue.'" United States v. Alzanki, 54 F.3d 994, 1005-06 (1st Cir. 1995), cert. denied, 516 U.S. 1111 (1996) (quoting United States v. Sepulveda, 15 F.3d 1161, 1183 (1st Cir. 1993); see also Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S.579, 591-595 (1993); Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 806 (3d Cir.1997). A trial judge must consider the following factors, which were established by the Supreme Court in Daubert, when addressing the admissibility of expert testimony:

> (1) whether the expert's technique or theory can be or has been tested – that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community.

Fed. R. Evid. 702, *Advisory Committee Notes to the 2000 Amendments*.[3]

However, "the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system." U.S. v. 14.38 Acres of Land, Situated in Leflore County, Mississippi, 80 F.3d 1074, 1078 (5th Cir. 1996). Indeed, the Court in Daubert stated: "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 595. The trial court's role has been described as follows:

> The fundamental question that a court must answer in determining whether a proposed expert's testimony will assist the trier of fact is "'[w]hether the untrained layman would be qualified to determine intelligently and to the best degree, the particular issue without enlightenment from those having a specialized understanding of the subject matter involved.'" United States v. Montas, 41 F.3d 775, 783 (1st Cir. 1994) (quoting Fed. R. Evid. 702 advisory committee's note), cert. denied, 514 U.S. 1121, 115 S. Ct. 1986, 131 L. Ed. 2d 873 (1995).

United States v. Shay, 57 F.3d 126, 132 (1st Cir. 1995). Rule 702 has a "liberal policy of admissibility." Ebenhoech v. Koppers Industries, Inc., 239 F.Supp.2d 455, 465 (D.N.J. 2002).

[3] Additional factors for analyzing the reliability of opinion testimony have since been identified. See e.g. Daubert v. Merrill Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1317 (9th Cir. 1995)(whether an expert is "proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying."); Claar v. Burlington N.R.R., 29 F.3d 499 (9th Cir. 1994) (whether the expert has accounted for obvious alternative explanations); see also In re: Paoli Railroad Yard PCB Litigation, 35 F.3d 717, 742 at n.8 (3rd Cir. 1994).

Additionally, regarding an expert's direct experience with the field to which the proffered opinion testimony is not determinative of admissibility:

> Rule 702 is not so wooden as to demand an intimate level of familiarity with every component of a transaction or device as a prerequisite to offering expert testimony. See Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 594, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993) (noting that the Rule 702 inquiry is "a flexible one"). When, as in this case, an expert is "qualified . . . by knowledge, skill, experience, training, or education," Fed. R. Evid. 702, he need not have had first-hand dealings with the precise type of event that is at issue. See, e.g., Diefenbach v. Sheridan Transp., 229 F.3d 27, 31 (1st Cir. 2000) (upholding district court's allowance of sea captain's expert testimony despite captain's lack of familiarity with the particular type of vessel on which plaintiff's injury took place).

Microfinancial, Inc. v. Premier Holidays Intern., Inc., 385 F.3d 72, 80 (1st Cir.2004). "The question, therefore, is whether the expert has good grounds for reaching his opinion." Ebenhoech, 239 F.Supp.2d at 466.

B. Mr. Lieberman Is Fully Qualified to Testify About the Metallurgical Aspects of the Surgical Screws At Issue In This Litigation

Mr. Lieberman has degrees in Metallurgical Engineering and Engineering Science. He has over forty-five years of professional experience working as a metallurgical engineer. Mr. Lieberman is not being proffered to offer opinions on fusion surgery or biomaterials. His opinion is regarding the strength of a metal screw. Given his lengthy history in metallurgical engineering, he is sufficiently qualified to render an opinion in this regard.

Synthes attempts to confuse the issues that are relevant to this issue by suggesting expertise in the areas of fusion surgery or biomaterials are necessary to understand the screw at issue. It is worth noting, Benjamin Barrall, the corporate designee for Synthes who was produced to answer all questions regarding the design, manufacture, and testing of the screws at issue is not a physician, has no medical degrees, and has only a Bachelor of Science degree in

Mechanical Engineering. Prior to joining Synthes in 2003, Mr. Barrall had no professional experience with regard to medical devices but rather worked on machinery and other metal devices. Nevertheless, Synthes deemed Mr. Barrall competent to testify in a manner that binds the company, with regard to the design, manufacture and testing of the screws at issue in this litigation. Synthes had three engineers provide signatures to approve of the designs for the screws at issue and the ATB System. None of these three individuals were physicians. Given this information, Synthes' representations to the Court that Mr. Lieberman cannot testify regarding the design and testing of the screws at issue because he lacks the necessary qualifications, seem disingenuous as the very people who design its products and are offered as the most knowledgeable individuals of these products have similar or indeed less qualifications than Mr. Lieberman.

Synthes has attempted to demonstrate, through its own experts, that Mr. Lieberman's opinions are not feasible. It has claimed that shot peening cannot work because of stress shielding, however, as noted above, none of their experts state that stress shielding will result from increased fatigue strength in the screws. They attempt to confuse the issue by referring to the strength of the plate or "the construct" rather than the screws. To the extent that Dr. Zardiackas claims that shot peening is not desirable for cancellous screws because of possible deformation, that is a metallurgical issue that is within Mr. Lieberman purview. Further, that simply goes to the credibility of the experts rather than admissibility. *See* Ebenhoech, 239 F.Supp.2d at 466 n.10. Similarly, as argued above, Mr. Lieberman's opinions regarding gray annodization and dye penetrant inspections are processes that are well within the scope of a metallurgical engineer's knowledge and expertise. Synthes' has failed to demonstrate that

knowledge of fusion surgery or biomaterials is necessary on the issue of making a more robust screw.

The unpublished opinion of Muller v. Synthes Corp., 2001 WL 521390 (N.D.Ill.2001) is distiguishable from the instant matter because the Synthes' product that broke in that case was the cervical spine locking plate ("CSLP") that spanned multiple vertebrae. The screws that held the plate in place do not appear to have failed in that case. Here, Mr. Lieberman has not rendered an opinion regarding the plate in the ATB System. Rather he has opined on the failed screws whose sole job was to hold the plate in place.

Synthes' motion aggressively attacks Mr. Lieberman's reports and his admitted lack of knowledge regarding medical issues. These attacks however, address credibility issues, not qualification issues because Synthes has failed to demonstrate how knowledge of fusion surgery or biomaterials is necessary for rendering the opinion that a more robust screw could have avoided the injury to Mr. Jones. Quite simply, Synthes has not demonstrated that Mr. Lieberman's opinions are unreliable and therefore its motion should be denied.

C. Mr. Lieberman's Opinions Are Admissible Because They Are Based Upon Well-Established and Widely Accepted Processes

The opinions of Mr. Lieberman satisfy the factors enunciated by Daubert, 509 U.S. at 593. More importantly, his opinions serve the basic function of the Daubert factors and Fed. R. Evid. 702, and demonstrate qualification, reliability, and fit. *See* Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir.2003). Synthes argues that Mr. Lieberman's opinions are not based upon reliable methodology claiming that his proposed alternatives have not been tested and do not "fit" the facts of this case. This is simply untrue. Synthes' own experts acknowledge that the processes suggested by Mr. Lieberman are well established serve

the purpose of increasing the fatigue strength of the screws – which is in direct contract to the position taken in Synthes' motion.

1. Mr. Lieberman's Alternative Design Methods Are Inherently Reliable Because They Are Based Upon Well-Established Processes In Metallurgical Engineering

As in previous arguments, Synthes asserts that Mr. Lieberman's failure to conduct testing on his proposed alternative design theories should constitute grounds for his preclusion. However, this argument is simply lacking in foundation. The processes suggested by Mr. Lieberman that could have increased the fatigue strength of the screws at issue are well known and have long been utilized in metallurgical engineering.

With regard to shot peening, the December 9, 2009 report of Synthes' expert Dr. Zardiackas states:

> The first solution to fatigue fracture of the cancellous screws as proposed by Mr. Lieberman is shot peening. While ***shot peening of metal does increase its fatigue strength without an increase in elastic modulus or ultimate tensile strength***, its use in this particular case is not advisable for a number of reasons. As described by Mr. Lieberman in his deposition, shot peening is a process by which high impact generally spherical particals impinge upon a metal surface to impart compressive stresses which raise the resistance to the initiation of a fatigue crack. ***This process is well known and used by many implant manufacturers including Synthes for certain applications***.

See Synthes' Exhibit I at p. 2 of the December 9, 2009 report (emphasis added). Similarly, with regard to gray anodization, Dr. Zardiackas states: "I believe Mr. Lieberman is referring to Type II titanium anodization which imparts a gray color to the surface, imparts increased lubricity, and ***increases the fatigue strength of titanium***." *See* Synthes' Exhibit I at p. 3 of the December 9, 2009 report (emphasis added). Synthes also feels that dye penetrant inspection has also not bee adequately tested, however, Dr. Zardiackas is familiar with the process and appears to be aware of its use in metallurgical engineering. His only dispute with the process is that the chemicals

used might not be biocompatible. However, as noted above, his report does not assert that a sterilization process could not sufficiently remove any and all hazardous chemicals. *See* Synthes' Exhibit I at p. 2 of the December 9, 2009 report.

Synthes' brief at page 36 states that Mr. Lieberman's opinion should be precluded because there is no scientific support to demonstrate that his alternative designs would "improve fatigue life as claimed by Mr. Lieberman." Synthes brief ignores the contents of their own expert report in trying to preclude Mr. Lieberman. Dr. Zardiackas demonstrates that the alternate processes which Synthes could have applied would increase the fatigue strength of the screws precisely because the methods are tested and well established in metallurgical engineering.

It is for the jury to determine assess credibility to the parties' respective experts in determining whether Plaintiffs' have successfully demonstrated that the Synthes' screws were defective. Mr. Lieberman is fully qualified to testify regarding his alternative designs and the methods he has suggested are well-established and require no speculation on the part of a jury.

2. Mr. Lieberman's Opinions Sufficiently "Fit" the Facts of This Case

Synthes repeats throughout its motion a fundamentally flawed notion, which in and of itself merits the denial of the summary judgment motion. Synthes asserts that "the breakage of the ATB's screws resulted from plaintiff's failure to achieve fusion rather than from any defect of the ATB." *See* Synthes' brief at p. 37. It is acknowledged that fusion had not been complete at the time the Synthes' screws failed, however, the screws failed well within the necessary time needed for the fusion to be complete. The ATB System did not provide sufficient time for the fusion to complete due to the screw failure and therefore the screws were defective.

Mr. Lieberman's opinion essentially asserts that his alternate design theories would have significantly improved the fatigue strength of the screws to prevent them from failing within the time parameters needed for fusion to take hold. To render this opinion, one does not need

expertise in the medical field or of surgical techniques, or biomaterials. The "race to fusion" that is emphasized by Synthes demonstrates why Mr. Lieberman's opinions are a perfect "fit" with the facts of this case. Had some simple, well-established engineering practices been adopted, screws that are fit to endure the "race to fusion" could have been produced and the injuries to Mr. Jones could have been avoided. Mr. Lieberman's familiarity with the "race to fusion" is of absolutely no relevance to the issues of his qualifications for the opinions he has rendered and for the inherent reliability of those opinions. The argument should be disregarded accordingly.

CONCLUSION

Based upon the foregoing, there are multiple issues of material fact that justify denying Synthes' motion for summary judgment as well the motion to preclude the testimony of Mr. Warren Lieberman. Plaintiffs Robert Jones and Krista Jones therefore respectfully request that the Court enter an Order denying the motions of defendants Synthes USA Sales, LLC and Synthes USA Products, LLC.

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